REMARKS

The Office Action of November 26, 2008, and the prior art applied therein have been carefully studied. The claims in the application are now claims 10, 11, 16-18 and 20-23, and these claims are believed and respectfully submitted to define patentable subject matter under Sections 102 and 103, warranting their allowance. Applicants respectfully request favorable reconsideration and allowance.

Some amendments are introduced into the claims above. Namely, "nephropathy" has been amended to "diabetic nephropathy or atherosclerotic nephropathy". The basis for the amendment is given in claims 16 and 17, and the recitation is also supported by a working example. The effect of the present invention was confirmed by using a mouse model in Example 1. The renal injury of this model mainly includes tubular atrophy or partial necrosis, showing ischemic renal injury resembling clinical atherosclerotic nephropathy or diabetes-induced atherosclerotic nephropathy (refer to paragraph [0039] of the present specification).

In addition, new claims 22 and 23 now more clearly specify that the effective dosage is based on the G-CSF itself, the only active agent disclosed in the present application for the described function.

Claims 10, 11, 16-18, 20 and 21 have been again rejected under Section 102 as anticipated by Shinshido. This rejection is again respectfully traversed for the reasons of record, respectfully repeated by reference, and also for the additional reasons set forth below.

Shishido et al treated 9 partients for end-stage renal failure (CRF) with G-CSF and found it an effective therapeutic agent for neutropenia and neutrophils dysfunction in such patients with end-stage renal failure (Abstract). CRF is an abbreviation of chronic renal failure and can be caused by a large number of various causes as stated in paragraph [0009] of the present specification.

In addition to the causes recited in paragraph [0009], causes of CRF include glomerulonephritis (refer to the Abstract of attached Reference 1: Yamada et al, Proceedings of the National Academy of Sciences of the United States of America (2005), 102(21), p.7736-7741); toxic nephropathy (refer to the Abstract of attached Reference 2: Glenda et al, Seminars in Nephrology (2003) (2003), 23(5), p.116-124); and IgA nephropathy (refer to the Abstract of attached Reference 3: Eiro et al, Nephron (2002), 90(4), p.432-441). Applicants are also enclosing a copy of Walser et al, American Journal of Kidney Diseases (1997), 29(4), p.503-513 (Reference 4), the abstract of which states that "Patients with any of four

different types of chronic renal failure (CRF) (glomerular disease, interstitial nephritis, diabetic nephropathy, or polycystic disease) were observed --".

Therefore, CRF is a generic catch phrase for a host of different conditions of renal failure caused by many different causes.[1] Based on the disclosure of Shishido, it is clear that those skilled in the art would not have expected that G-CSF would be effective for proliferating or regenerating renal tissue of diabetic nephropathy or atherosclerotic nephropathy. Particularly, the treatment of neutropenia and neutrophils dysfunction in patients with end stage renal failure, which is the result of Shishido, is entirely irrelevant to the proliferation or regeneration of a renal tissue of diabetic nephropathy or atherosclerotic nephropathy. It is clear that the present invention is novel over Shishido.

Applicants' claims have been amended to specify that the treatment claimed is for diabetic nephropathy or atherosclerotic nephropathy, something neither disclosed nor made obvious by Shishido.

Withdrawal of the rejection is in order and is respectfully requested.

[1] In general, legally, a generic disclosure does not anticipate a species.

Claims 10, 11, 16-18, 20 and 21 have been again rejected under Section 102 as anticipated by Fukuda. This rejection is again respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

Fukuda describes in paragraph [0017] that "G-CSF of the present invention is applicable as a remedy for --- ischemic renal disease".

The term "renal disease" of course includes a large number of diseases of various origins and is even broader than "chronic renal failure". As stated above, applicants' claims have been amended to specify diabetic nephropathy or atherosclerotic nephropathy. Fukuda is entirely silent about diabetic nephropathy or atherosclerotic nephropathy and does not put the person skilled in the art in possession of the claimed invention.

Secondly, considering the descriptions in paragraphs [0016] and [0018] of Fukuda and the Fukuda claims, the recitation "G-CSF of the present invention" in paragraph [0017] of Fukuda must be understood to mean "G-CSF in combination with HGF of the present [Fukuda] invention".

Fukuda thus relates to a method for treating a wide variety of ischemic diseases by administering a combination of both G-CSF and hepatocyte growth factor (HGF) (Claim 1).

Administration of G-CSF and HGF contributes to vasculogenesis in a patient, in the treatment of ischemic diseases (paragraph [0058] of Fukuda). It is essential in the Fukuda treatment to administer both G-CSF and HGF. Therefore, the treatment of Fukuda is entirely different from that of the present invention, which relates to repairing/regenerating renal tissue of diabetic nephropathy or atherosclerotic nephropathy by administering G-CSF only. Fukuda does not disclose, suggest, or teach the use of G-CSF in repairing/regenerating renal tissue of diabetic nephropathy or atherosclerotic nephropathy.

Regarding the combination of G-CSF and HGF, the examiner's position is respectfully submitted to be incorrect. Paragraph [0057] indeed states that "G-CSF and HGF can be prepared and administered as a single preparation. Alternatively, they can be prepared separately, and administered on different occasions." This recitation clearly means, however, that the administration of both G-CSF and HGF is necessary for the treatment even if they are administered together or separately, and it does not mean that only G-CSF need be administered, or that the administration of only G-CSF can be effective. Fukuda does not disclose the administration of G-CSF in an effective amount, as claimed, and also does not make the separate administration of G-CSF in an effective

amount obvious. In other words, the only effective amount for treatment disclosed by Fukuda requires both G-CSF and HGF.

Withdrawal of the rejection is in order and is respectfully requested.

Applicants believe and respectfully submit that all issues raised in the Office Action are addressed above in a manner which should lead to allowance of the present application. Favorable reconsideration and allowance earnestly solicited.

Respectfully submitted,

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